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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,721	01/15/2004	Masao Hashimoto	163852020600	3854
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MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 300 MCLEAN, VA 22102			EXAMINER TOTH, KAREN E	
			ART UNIT 3736	PAPER NUMBER

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,721

Applicant(s)

HASHIMOTO ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because of the following minor informalities:

Element 50, shown in figures 3 and 4, is never described in the specification. It is suggested that this be added, particularly because the item to which it appears to refer is mentioned several times, e. g., “the arm extending from the elbow to the wrist” and “the wrist of the subject is securely fixed”(paragraph 0047), and “moved down to the wrist” (paragraph 0050).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

2. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent Application No. 10/758600. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant application claims a pulse wave measuring apparatus comprising a sensor unit with a pressure sensitive part; a living organism fixing device or fixing stand; a pressure part to press the pressure sensitive part against the organism; and a pressure part control unit located in the fixing stand.

Copending Application No. 10/758600 claims a pulse wave measuring apparatus comprising a sensor unit with a pressure sensitive portion; a living organism fixing device or fixing stand; a fastening band that connects the sensor unit to the fixing stand and is used for activating by pressing said sensor unit to the organism (pressure part); and a tensioning part for pulling said fastening band that is located in the fixing stand (pressure part control unit).

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Line 3 of Claim 1 states, "a living organism fixing device for fixing a living organism." The examiner suggests that this be changed to --a living organism fixing device adapted for fixing a living organism--.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

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Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pond'205 (US Patent 183205).

Pond'205 discloses a sphygmograph comprising a sensor unit (element A) with a pressure sensitive part (element B) (see figures 2 and 3); and a device for fixing a living organism (elements L and M). Said fixing device is used to hold the pressure sensitive part of the sensor unit against the living organism (page 2, right column; Figure 1), and is controlled by screws (element N).

7. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Sato'061 (US Patent Application Publication 2004/0193061).

Sato'061 discloses a pulse wave detecting apparatus that comprises a sensor unit (element 1) and a fixing stand (elements 2 and 7) for holding the wrist of the subject (paragraph 0062); said sensor unit includes a pressure sensor array (element 11) which is pressed against the wrist of the subject by a pressurization cuff (element 13) (paragraph 0065). Within the fixing stand are found pumps (elements 14 and 15) for controlling the pressure of the pressurization cuff (paragraph 0066).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

8. Claims 2-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Sato'061.

Regarding Claim 2, as discussed in paragraph 7 above, Sato'061 discloses that the fixing stand (element 7) also includes an analog/digital converter (element 19) for processing an output signal from the sensor unit (paragraph 0066).

Regarding Claim 3, Sato'061 further discloses that said sensor unit (element 1) includes an array of pressure sensors (element 11). Sato'061 also discloses the presence of a multiplexer (element 12), located in the sensor unit, is used to process voltage signals outputted by pressure sensors (Figure 1, and paragraph 0088).

Regarding Claim 4, Sato'061 further discloses that the component used as a pressure part is an inflatable cuff (element 13) that includes an air bag (paragraph 0065). Controls for said inflatable pressurization cuff include positive and negative pressure pumps (elements 14 and 15, respectively) that are used to inflate and deflate the cuff, and a control section (element 17) and communication circuit (element 18) (paragraph 0066).

Regarding Claim 5, Sato'061 further discloses that additional components of the pulse wave apparatus include a central processing unit (CPU) (element 20) that processes the signals from the pressure sensors (element 26), a display that outputs information (element 24), and a port for insertion of a Universal Series Bus (USB) cable (shown as element 4 in Figures 2 and 3) (paragraphs 0063, 0067 and 0079). The CPU and display may be located in the fixing stand (element 2) of the apparatus (paragraph 0068).

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9. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Hashimoto'199 (US Patent Application Publication 2004/0010199).

Hashimoto'199 discloses an apparatus for monitoring pulse waves that comprises a sensor unit (element 1) that has a pressure sensitive element (paragraph 0038) including a sensor (element 11) (paragraph 0044). The apparatus may also include a wrist fixture (element 3) that holds the wrist of the subject and is used to fix the base of the sensor unit to it (paragraph 0113); a belt (element 23) is used to retain the location of the sensor unit upon the wrist of the subject with a suitable amount of pressure (paragraph 0111). Said belt is tightened by a pulling mechanism (element 31) located on the wrist fixture (paragraphs 0114 to 0116).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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12. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasawa'084 (US Patent 4844084) in view of Hon'792 (US Patent 5025792).

Yamasawa'084 discloses a blood pressure meter comprising a sensor unit (elements 15 and 16) and a fixing device for fixing a living organism (elements 1 and 2) (Figure 1). Said fixing device uses a pressure cuff (element 8) to press said sensors against the living organism for the purpose of measuring the pulse (column 3, lines 19-20). The pressure of the pressure cuff is controlled by a motor (element 26) and valve (element 27) that fill said cuff with pressurized air (column 3, lines 54-59), where said valve and motor are located within the casing (element 1) of the unit (column 3, lines 16-18). Yamasawa'084 does not disclose the use of pressure-sensitive parts for measuring pulse waves as part of the sensor unit.

Hon'792 teaches a blood pressure measuring apparatus comprising a sensor unit (Figure 4) that includes a pressure transducer (element 24); and a fixing device to fix a living subject (elements 10 and 40).

It would have been obvious to one skilled in the art at the time the invention was made to have formed the pulse measuring apparatus of Yamasawa'084 with the pressure-sensitive transducer of Hon'792 because it is the substitution of one equivalent sensor for another.

Regarding Claim 2, Yamasawa'084 further teaches that an analog-to-digital converter (element 22) is part of the processing of the pressure signals detected by the sensor unit (column 4, lines 10-11).

Regarding Claim 3, Yamasawa'084 further teaches that the pressure sensitive part includes a plurality of sensors in array (elements 15 and 16). Yamasawa'084 also teaches a multiplexing unit (element 12) for processing the signal outputs from the pressure sensitive part (Figure 3) that is located within the casing of the unit (element 1).

Regarding Claim 4, Yamasawa'084 further teaches that the pressure part is an expandable cuff (element 8) formed by a base sheet (element 82) and a bag skin (element 83) (column 3, lines 23-25). Said cuff is filled and emptied of pressurized air by operation of a motor (element 26), motor drive circuit (element 25), vent (element 28), and rapid vent valve drive circuit (element 27) (column 3, lines 54-59), which are all located within the casing of the unit (element 1).

Regarding Claim 5, Yamasawa'084 further teaches that the unit's casing (element 1) also houses a display unit (element 4) and switches for external input from a user (elements 5 and 6) (column 3, lines 13-15). Yamasawa'084 also teaches that the basic signal processing functions for determining blood pressure are performed within the unit's casing (column 4, lines 25-28).

13. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasawa'084 in view of Hon'792 as applied to claims 1-5 above, and further in view of Kondo'775 (US Patent Application Publication 2002/0151775).

Yamasawa'084 in view of Hon'792 teaches all the elements of the current invention as discussed in paragraph 12, except for locating the display unit and operating unit on the sensor unit of the apparatus.

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Kondo'775 teaches a biometric measuring device comprising a sensor unit (element 10) that is pressed to a subject by a fixing device (element 20). Said sensor unit also houses a display (element 113) and means for providing external input (elements 116 and 117), so that the measurements may be easily viewed and, if needed, altered (paragraph 0071).

It would have been obvious to one skilled in the art at the time the invention was made to have formed the pulse wave measuring apparatus of Yamasawa'084 in view of Hon'792 with the display and external input means of Kondo'775 to allow for ease of viewing and providing input.

Regarding Claim 7, Yamasawa'084 in view of Hon'792 discloses all the elements of the current invention as discussed in paragraph 12 above except for locating the arithmetic processing unit, display unit, and operating unit on the sensor unit of the apparatus.

Kondo'775 further teaches that the signal processing operations (element 110) of the biometric apparatus are located within the housing (element 10) (paragraph 0070).

It would have been obvious to one skilled in the art at the time the invention was made to have formed the pulse wave measuring apparatus of Yamasawa'084 in view of Hon'792 with the display, external input means, and signal processing operations of Kondo'775, meaning within the sensor unit for ease of viewing and providing input, and consolidating the signal processing operation between sensor and display.

14. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato'061 in view of Hashimoto'199.

Regarding Claim 6, Sato'061 discloses all the elements of the current invention as discussed in paragraphs 7 and 8 above except for locating the display unit and operating unit on the sensor unit of the apparatus.

Hashimoto'199 teaches an apparatus for measuring pulse waves, as discussed in paragraph 9 above, that further includes a display (element 113) mounted on the sensor unit (element 1), as shown in Figure 14, for displaying results of measurements taken by the sensor unit. Hashimoto'199 further teaches that the CPU (element 101) used for controlling the sensor unit is located within said sensor unit (paragraphs 0049-0052), and that said CPU may be connected to an external device such as a personal computer (paragraph 0054).

It would have been obvious to one skilled in the art at the time the invention was made to have formed the pulse wave apparatus of Sato'061 with the display unit located within the sensor unit to allow display of data, and provided means for connecting the operating unit of the sensor to an external device to allow additional communication and result processing, as taught by Hashimoto'199.

Regarding Claim 7, Sato'061 discloses all the elements of the current invention as discussed in paragraph 8 above except for locating the arithmetic processing unit, display unit, and operating unit on the sensor unit of the apparatus.

Hashimoto'199 teaches an apparatus for measuring pulse waves, as discussed in paragraph 9 above, that further includes a display (element 113) mounted on the sensor unit (element 1), as shown in Figure 14, for displaying results of measurements taken by the sensor unit. Hashimoto'199 further teaches that the CPU (element 101)

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used for controlling the sensor unit is located within said sensor unit (paragraphs 0049-0052), and that said CPU may be connected to an external device such as a personal computer (paragraph 0054). Also located within said sensor unit are memory (element 102) and an operation unit (element 104), which in combination with the CPU, are used to execute various operations (Figure 3; paragraphs 0049-0053).

It would have been obvious to one skilled in the art at the time the invention was made to have formed the pulse wave apparatus of Sato'061 with the display unit located within the sensor unit to allow display of data, provided means for connecting the operating unit of the sensor to an external device to allow additional communication and result processing, and located the signal processing elements in the sensor unit, as taught by Hashimoto'199.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5494043 to O'Sullivan, which discloses a pulse wave measuring apparatus.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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